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Sustaining Positive Engagement and Recovery (SUPEREDEN) - Improving social recovery in young people with emerging severe social disability

Submission date
26/06/2012

Recruitment status
No longer recruiting

Registration date
26/06/2012

Overall study status
Completed

Last Edited
15/02/2018

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Psychosis is a mental health problem that causes people to lose contact with reality, and can involve hallucinations or delusions. Social recovery is a return to effective social functioning after treatment (engaging in constructive leisure and social activity and return to education or work). Cognitive behavioural therapy (CBT) is a talking therapy that is most commonly used to treat anxiety and depression, but can be useful for other mental health problems. The aim of this study is to assess whether Social Recovery Orientated Cognitive Behavioural Therapy (SRCBT) increases the time patients spend in structured activity and reduces their levels of depression and hopelessness.

Who can participate?
150 patients with non-affective psychosis (psychosis that is not related to emotions or moods)

What does the study involve?
Participants are randomly allocated to either the control or the experimental group. The experimental group receive regular SRCBT for 9 months. The control group receive treatment as usual. All participants are assessed at the start of the study and after 9 and 15 months.

What are the possible benefits and risks of participating?
We have found from previous studies that most participants welcome participation in research studies, as even contact with the researchers conducting assessments offers support from concerned and trained professionals above that provided in standard care. This is potentially a very important study which could have important implications for clinical practice in mental health services.

Where is the study run from?
The study is sponsored by Birmingham and Solihull Mental Health NHS Foundation trust (BSMHFT) and recruitment will take place in Birmingham, Norfolk and Lancashire Early Intervention Services.

When is the study starting and how long is it expected to run for?
July 2012 to March 2014

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Linda McCarthy
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8645

Study information

Scientific Title
Sustaining Positive Engagement and Recovery (SUPEREDEN) - the next step after Early Intervention for Psychosis. Study 3: Improving social recovery in young people with emerging severe social disability: A proof of principle randomised controlled trial

Acronym
SuperEDEN 3

Study objectives
The aim will be to assess the feasibility of Social Recovery orientated Cognitive Behavioural Therapy in a large multicentre trial.

Primary hypothesis:
The intervention will lead to improvements in the time spent in structured activity.

Secondary hypotheses that the intervention will:
1. Reduce levels of depression and hopelessness and
2. Improve negative symptoms

A detailed analysis of adherence will help clarify details of training and supervision and assess the ability of staff from different professional backgrounds to apply this intervention across centres.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee West Midlands The Black Country, 10/04/2012, ref: 05/Q0102/44MHRNC

Study design
Randomised; Interventional; Design type: Process of Care, Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Mental Health Research Network; Subtopic: Psychosis; Disease: Psychosis

Interventions
Three UK sites will be taking part: Birmingham, Lancashire and Norwich.

Participants will be randomly allocated to two groups:
1. Social Recovery Orientated Cognitive Behavioural Therapy + Treatment As Usual (SRCBT +

TAU)
2. TAU only

Participants randomly allocated to the SRCBT + TAU group will receive SRCBT over 9 months by a qualified psychologist or an accredited CBT therapist. Sessions will be held either weekly or fortnightly and the therapy will be delivered in 3 stages.

Follow Up Length: 15 month(s)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Time Use Survey (Short, 2006) assessed at 9 and 15 months

Secondary outcome measures
The Positive and Negative Syndrome Scale (PANSS)

Overall study start date
01/07/2012

Completion date
31/03/2014

Eligibility

Key inclusion criteria
1. Patients with non-affective psychosis
2. Clients of Norfolk, Birmingham and Lancashire early intervention services
3. Clients who show a low level of structured activity after at least one year of treatment (defined as 30 hours or less per week)
4. Clients who have been with EIS between one and two years
5. Male & Female; Upper Age Limit 35 years ; Lower Age Limit 16 years

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 150; UK Sample Size: 150

Key exclusion criteria

1. Clients who were part of the original National EDEN Cohort
2. Clients who do not speak English
3. Clients who are considered too unwell by their care coordinators will not be approached by the study team

Date of first enrolment
01/07/2012

Date of final enrolment
31/03/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Psychology
Birmingham
United Kingdom
B15 2TT

Sponsor information

Organisation
Birmingham and Solihull Mental Health NHS Foundation Trust (UK)

Sponsor details
Research & Innovation, Radclyffe House
66-68 Hagley Road
Birmingham
United Kingdom
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Sponsor type
Charity

ROR
https://ror.org/00cjeg736

Funder(s)

Funder type
Government

Funder Name
Programme Grants for Applied Research; Grant Codes: RP-PG-0109-10074

Alternative Name(s)
NIHR Programme Grants for Applied Research, PGfAR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2018		Yes	No